

## **APPENDIX B**

to declaration by Tetsuya Gatanaga, Ph.D.

*Data from Clinical Trial, Protocol AIT-PAN-20*

Meyer Pharmaceuticals LLC  
BB-IND-6288  
Protocol AIT-PAN-201

Survival

CYTOIMPLANT

Site/Patient Number	Patient Initials	Age (years)	Sex	Baseline Disease Stage	Date of Randomization	Date of Death	Survival Days (as of 10-Nov-99)	Status (as of 10-Nov-99)
01-002	MSM	67	F	Stage IV, T4 N1 MX	27-Jan-99	24-May-99	117	Deceased
01-004	HGK	73	M	Stage IV, T4 N0 M0	09-Mar-99	24-Aug-99	168	Deceased
01-005	MAW	67	F	Stage IV, T4 N0 MX	31-Mar-99	N/A	224+	Off Study
01-006	LCT	64	F	Stage IV, T4 N1 MX	01-Apr-99	14-Jul-99	104	Deceased
01-009	EAR	58	F	Stage IV, T4 N1 M1	20-Apr-99	N/A	204+	Off Study
01-010	DLW	78	M	Stage III, T3 N1 MX	30-Jul-99	N/A	103+	On Study
02-052	A-P	65	F	Stage IV, T4 N0 M0	25-Feb-99	22-May-99	86	Deceased
02-053	S-M	33	F	Stage IV, T4 NX M1	29-Mar-99	21-Jun-99	84	Deceased
02-054	CEM	58	M	Stage IV, T4 N1 M1	27-Apr-99	26-Jun-99	60	Deceased
03-101	REW	54	M	Stage III, T3 N1 M0	08-Feb-99	N/A	275+	On Study
03-102	DLD	53	M	Stage IV, T4 N1 M0	18-Mar-99	N/A	237+	Off Study
03-104	VFB	85	F	Stage IV, T4 N0 M0	04-May-99	N/A	190+	On Study
03-105	AMS	79	M	Stage IV, T4 N1 M1	14-Jun-99	14-Oct-99	122	Deceased
03-108	WLG	57	M	Stage IV, T4 N0 M1	07-Sep-99	N/A	64+	On Study
04-151	M-B	78	F	Stage II, T3 N0 M0	11-Mar-99	20-May-99	70	Deceased
04-152	EMD	71	F	Stage III, T3 N1 M0	09-Jun-99	N/A	154+	Off Study
05-203	BFB	65	F	Stage IV, T4 N1 MX	07-Jul-99	01-Aug-99	25	Deceased
05-204	PAQ	70	M	Stage IV, T4 N0 M1	19-Jul-99	N/A	114+	On Study
05-206	RES	78	M	Stage II, T3 N0 M0	25-Aug-99	N/A	77+	On Study
05-207	RJW	74	M	Stage III, T2 N1 M0	14-Sep-99	N/A	57+	On Study
05-208	MJS	69	F	Stage II, T3 NX MX	18-Oct-99	N/A	23+	On Study
06-251	FJM	63	M	Stage III, T3 N1 M0	15-Oct-99	N/A	26+	On Study
08-351	P-F	63	F	Stage IV, T4 N1 MX	12-Oct-99	N/A	29+	On Study

\* see footnotes on next page

Meyer Pharmaceuticals LLC

BB-IND-6288

Protocol AIT-PAN-201

### Survival

### Gemcitabine

Site/Patient Number	Patient Initials	Age (years)	Sex	Baseline Disease Stage	Date of Randomization	Date of Death	Survival Days (as of 10-Nov-99)	Status (as of 10-Nov-99)
01-001	CDR	81	M	Stage IV, T4 N1 M0	10-Dec-98	03-Nov-99	328	Deceased
01-003	WMH	55	F	Stage III, T3 N1 M0	15-Feb-99	N/A	268+	Off Study
01-007	REH	53	M	Stage IV, T4 N0 MX	06-Apr-99	N/A	218+	On Study
01-008	ADC	59	F	Stage IV, T4 N1 M1	13-Apr-99	17-Aug-99	126	Deceased
02-051	CHS	75	M	Stage IV, T4 NX M1	11-Feb-99	N/A	272+	Off Study
02-055	LDR	50	M	Stage IV, T4 N1 M0	10-Sep-99	N/A	61+	On Study
03-103	EFK	75	F	Stage IV, T4 N0 MX	23-Apr-99	N/A	201+	On Study
03-106	R-M	72	M	Stage IV, T3 N0 M1	09-Jul-99	N/A	124+	On Study
03-107	CGD	60	F	Stage II, T3 N0 M0	19-Jul-99	N/A	114+	Off Study
05-201	JLB	79	F	Stage III, T1 N1 M0	09-Jun-99	N/A	154+	Off Study
05-202	D-S	59	M	Stage IV, T3 N0 M1	25-Jun-99	N/A	138+	On Study
05-205	EMS	72	F	Stage IV, T4 N0 M0	04-Aug-99	N/A	98+	On Study
07-301	RIW	71	F	Stage IV, T2 N1 M1	18-Oct-99	N/A	23+	On Study

Survival Days = Date of Death (or 10-Nov-99) - Randomization Date

N/A = Not Applicable (death not reported for patient as of 10-Nov-99)

Patients 003 and 107 withdrew from the study upon randomization to Gemcitabine.

**Time to Treatment Failure  
CYTOIMPLANT**

Site/Patient Number	Patient Initials	Age (years)	Sex	Baseline Disease Stage	Date of Randomization	Date of Treatment Failure	Time to Treatment Failure (days)	Reason for Treatment Failure
01-002	MSM	67	F	Stage IV, T4 N1 MX	27-Jan-99	27-Apr-99	90	Progressive Disease
01-004	HGK	73	M	Stage IV, T4 N0 M0	09-Mar-99	02-Jun-99	85	Progressive Disease
01-005	MAW	67	F	Stage IV, T4 N0 MX	31-Mar-99	07-Jul-99	98	Progressive Disease
01-006	LCT	64	F	Stage IV, T4 N1 MX	01-Apr-99	19-May-99	48	Progressive Disease
01-009	EAR	58	F	Stage IV, T4 N1 M1	20-Apr-99	21-Jul-99	92	Progressive Disease
01-010	DLW	78	M	Stage III, T3 N1 MX	30-Jul-99	25-Oct-99	87	Progressive Disease
02-052	A-P	65	F	Stage IV, T4 N0 M0	25-Feb-99	22-May-99	86	Death
02-053	S-M	33	F	Stage IV, T4 NX M1	29-Mar-99	21-Jun-99	84	Death
02-054	CEM	58	M	Stage IV, T4 N1 M1	27-Apr-99	27-May-99	30	Progressive Disease
03-101	REW	54	M	Stage III, T3 N1 M0	08-Feb-99	28-Sep-99	232	Progressive Disease
03-102	DLD	53	M	Stage IV, T4 N1 M0	18-Mar-99	25-Jun-99	99	Progressive Disease
03-104	VFB	85	F	Stage IV, T4 N0 M0	04-May-99	25-Oct-99	174	Progressive Disease
03-105	AMS	79	M	Stage IV, T4 N1 M1	14-Jun-99	16-Jul-99	32	Progressive Disease
03-108	WLG	57	M	Stage IV, T4 N0 M1	07-Sep-99	N/A	N/A	
04-151	M-B	78	F	Stage II, T3 N0 M0	11-Mar-99	20-May-99	70	Death
04-152	EMD	71	F	Stage III, T3 N1 M0	09-Jun-99	10-Aug-99	62	Progressive Disease
05-203	BFB	65	F	Stage IV, T4 N1 MX	07-Jul-99	01-Aug-99	25	Death
05-204	PAQ	70	M	Stage IV, T4 N0 M1	19-Jul-99	N/A	N/A	
05-206	RES	78	M	Stage II, T3 N0 M0	25-Aug-99	N/A	N/A	
05-207	RJW	74	M	Stage III, T2 N1 M0	14-Sep-99	N/A	N/A	
05-208	MJS	69	F	Stage II, T3 NX MX	18-Oct-99	N/A	N/A	
06-251	FJM	63	M	Stage III, T3 N1 M0	15-Oct-99	N/A	N/A	
08-351	P-F	63	F	Stage IV, T4 N1 MX	12-Oct-99	N/A	N/A	

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Protocol AIT-PAN-201

**Time to Treatment Failure**  
**Gemcitabine**

Site/Patient Number	Patient Initials	Age (years)	Sex	Baseline Disease Stage	Date of Randomization	Date of Treatment Failure	Time to Treatment Failure (days)	Reason for Treatment Failure
01-001	CDR	81	M	Stage IV, T4 N1 M0	10-Dec-98	07-Apr-99	118	Progressive Disease
01-003	WMH	55	F	Stage III, T3 N1 M0	15-Feb-99	23-Feb-99	8	Patient withdrew consent
01-007	REH	53	M	Stage IV, T4 N0 MX	06-Apr-99	11-Jun-99	66	Progressive Disease
01-008	ADC	59	F	Stage IV, T4 N1 M1	13-Apr-99	17-Aug-99	126	Death
02-051	CHS	75	M	Stage IV, T4 NX M1	11-Feb-99	21-Sep-99	222	Progressive Disease
02-055	LDR	50	M	Stage IV, T4 N1 M0	10-Sep-99	N/A	N/A	
03-103	EFK	75	F	Stage IV, T4 N0 MX	23-Apr-99	N/A	N/A	
03-106	R-M	72	M	Stage IV, T3 N0 M1	09-Jul-99	N/A	N/A	
03-107	CGD	60	F	Stage II, T3 N0 M0	19-Jul-99	19-Jul-99	0	Patient withdrew consent
05-201	JLB	79	F	Stage III, T1 N1 M0	09-Jun-99	29-Jul-99	50	Patient withdrew consent
05-202	D-S	59	M	Stage IV, T3 N0 M1	25-Jun-99	N/A	N/A	
05-205	EMS	72	F	Stage IV, T4 N0 M0	04-Aug-99	N/A	N/A	
05-201	RIV	71	F	Stage IV, T2 N1 M1	18-Oct-99	N/A	N/A	

Time to Treatment Failure = Date of Treatment Failure - Date of Randomization

N/A = Not Applicable (no Treatment Failure as of 10-Nov-99)

Patients 003 and 107 withdrew from the study upon randomization to Gemcitabine.

Patient 201 refused to continue therapy.

AE/SAE Listings  
Adverse Events Possibly/Probably Related to Injection Procedure and/or Study Drug

Randomized Treatment: Cytoimplant

Investigator	Pat Init	Date of 1st Treatment	Date of Last Treatment	Date of Onset	Adverse Event	SAE Number	Date of Resolut.	Severity	Relationship	
									Injection Procedure	Study Drug
1/HAWES, ROBERT	2 MSW	27JAN1999	02FEB1999	-	15APR1999 VOMITING	1999-WC0346	18MAY1999	Sev	N/A	Poss
	10 DLW	30JUL1999	25AUG1999	-	ABDOMINAL PAIN	1999-WC0346	18MAY1999	Sev	N/A	Poss
2/ERICKSON, RICHARD	52 A-P	25FEB1999	08MAR1999	-	09MAR1999 CHILLS		22MAY1999	Mld	Poss	Poss
	53 S-M	29MAR1999	06APR1999	-	15APR1999 FEVER		29APR1999	Mld	Poss	Poss
	54 CEM	27APR1999	04MAY1999	-	04MAY1999 FEVER		26JUN1999	Mld	Poss	Poss
3/KOZAREK, RICHARD	101 REM	08FEB1999	17FEB1999	21JUL1999	17FEB1999 HOT FLASH		17FEB1999	Mld	Prob	Prob
					LOW BACK PAIN		22FEB1999	Mod	Prob	Prob
					OBSTIPATION		23FEB1999	Mod	Poss	Poss
					DARK URINE		22FEB1999	Mod	Prob	Poss
					18FEB1999 UPPER GIRTH PAIN		05APR1999	Mod	Prob	Prob
					DECREASED APPETITE		22JUL1999	Mld	Prob	Poss
					20FEB1999 CONSTIPATION		22FEB1999	Mod	Poss	Poss
					23FEB1999 PANCREATIC INFLAMMATION		05APR1999	Mod	Prob	Prob
					BACK PAIN		03MAR1999	Sev	Poss	Poss
					04MAR1999 BACK PAIN		22JUL1999	Mod	Poss	Poss
					24MAR1999 NAUSEA		06APR1999	Sev	Prob	Poss
					VOMITING		06APR1999	Mod	Prob	Prob
102 DLD		18MAR1999	24MAR1999	-	30MAR1999 GASTRIC BURNING		1999-WC0263	Sev	Prob	Poss
					30MAR1999 GASTRIC OUTLET OBSTRUCTION		06APR1999	Sev	Prob	Poss
					10MAY1999 EPIGASTRIC BURNING		12MAY1999	Mod	Prob	Unk
					10MAY1999 EPIGASTRIC DISCOMFORT		24MAY1999	Mod	Unk	Unk
104 VFB		04MAY1999	10MAY1999	20SEP1999	10MAY1999 EPIGASTRIC BURNING		12MAY1999	Mod	Prob	Unk
					10MAY1999 EPIGASTRIC DISCOMFORT		24MAY1999	Mod	Unk	Unk

Date of Last Treatment (Cytoimplant patients) = - ==> Patient not treated with second Cytoimplant as of data cut-off.  
Date of Resolution = - ==> if date is not given, event is ongoing or date of resolution is unavailable.  
Special Missing values: N = Not Applicable; D = Not Done; A = Not Available; U = Unknown  
All Adverse Events associated with an SAE number have been reported as a Serious Adverse Event only if YES is noted in the Serious column.  
More than one adverse event may have been reported with an SAE. These events are the signs and symptoms of the diagnosis.

AE/SAE Listings  
Adverse Events Possibly/Probably Related to Injection Procedure and/or Study Drug

Randomized Treatment: Cytointplant

Investigator	Pat Init	Date of 1st Treatment	Date of Last Treatment	Date of Onset	Adverse Event	SAE Number	Date of Resolut.	Severity	Relationship	
									Injection Procedure	Study Drug
3/KOZAREK, RICHARD	104 VFB	04MAY1999	10MAY1999	20SEP1999	11MAY1999 FEVER 37.7 C NAUSEA VOMITING CHILLS DIARRHEA ABDOMINAL PAIN DEHYDRATION NAUSEA/VOMITING	1999-WC0391 1999-WC0391	12MAY1999 12MAY1999 12MAY1999 12MAY1999 12MAY1999 12MAY1999 12MAY1999 12MAY1999 12MAY1999 12MAY1999	Mod Sev Mod Mod Mod Mod Mod Mod Mod Mod	Prob Prob Prob Prob Prob Prob Prob Prob Prob Prob	Prob Prob Prob Prob Prob Prob Prob Prob Prob Prob
4/GRESS, FRANK	151 M-8	11MAR1999	22MAR1999	- 23SEP1999	19AUG1999 FEVER - 23SEP1999 INCREASE IN TEMPERATURE GASSINESS NAUSEA VOMITING ABDOMINAL DISCOMFORT	30MAR1999	17AUG1999 17AUG1999	Mod Mod Mod Mod Mod Mod Mod	Poss Poss Poss Poss Poss Poss Poss	Unlk Unlk Unlk Unlk Unlk Unlk Unlk
5/NGUYEN, CUONG	204 PAQ	19JUL1999	27JUL1999	- 28JUL1999 - 29JUL1999 - 15OCT1999	29JUL1999 DIARRHEA DIARRHEA LOSS OF APPETITE PANCREATITIS FECAL INCONTINENCE	01AUG1999 02AUG1999	Mod Mod Mod Mod Mod Mod	Poss Poss Poss Poss Poss Poss	Poss Poss Poss Poss Poss Poss	Unlk Unlk Unlk Unlk Unlk Unlk
8/FAIGEL, DOUGLAS O.	351 P-F	12OCT1999	19OCT1999	- 19OCT1999	19OCT1999 NAUSEA NAUSEA	19OCT1999 29OCT1999	Mod Mod	Poss Poss	Poss Poss	Poss Poss

Date of Last Treatment (Cytointplant patients) = - ==> Patient not treated with second Cytointplant as of data cut-off.  
Date of Resolution = - ==> if date is not given, event is ongoing or date of resolution is unavailable.  
Special Missing values: N = Not Applicable; D = Not Done; A = Not Available; U = Unknown  
All Adverse Events associated with an SAE number have been reported as a Serious Adverse Event only if YES is noted in the Serious column.  
More than one adverse event may have been reported with an SAE. These events are the signs and symptoms of the diagnosis.

AE/SAE Listings  
Adverse Events Possibly/Probably Related to Injection Procedure and/or Study Drug

Randomized Treatment: Cytoimplant

Investigator	Pat Init	Date of 1st Treatment	Date of Last Treatment	Date of Onset	Adverse Event	SAE Number	Date of Resolut.	Severity	Relationship to:	
									Injection Procedure	Study Drug
8/FAIGEL, DOUGLAS O.	351	P-F	12OCT1999	19OCT1999	-	19OCT1999	ABDOMINAL TENDERNESS	29OCT1999	Mld	Poss
									Poss	

Date of Last Treatment (Cytoimplant patients) = - ==> Patient not treated with second Cytoimplant as of data cut-off.  
Date of Resolution = - ==> if date is not given, event is ongoing or date of resolution is unavailable.  
Special Missing values: N = Not Applicable; D = Not Done; A = Not Available; U = Unknown  
All Adverse Events associated with an SAE number have been reported as a Serious Adverse Event only if YES is noted in the Serious column.  
More than one adverse event may have been reported with an SAE. These events are the signs and symptoms of the diagnosis.





AE/SAE Listings  
Adverse Events Possibly/Probably Related to Injection Procedure and/or Study Drug

Randomized Treatment: Gemcitabine

Investigator	Pat Init	Date of Rand	Date of 1st Treatment	Date of Last Treatment	Date of Onset	Adverse Event	SAE Number	Date of Resolut.	Severity	Relationship	
										Injection Procedure	Study Drug
1/HAWES, ROBERT	1 CDR 7 REH	10DEC1998 06APR1999	18DEC1998 09APR1999	22OCT1999 16AUG1999	15OCT1999	URC 1.3 LOW		22OCT1999	Mod	N/A	Prob
						DECREASED		20MAY1999	Mod	N/A	Prob
						HEMOGLOBIN 6.0					
						DECREASED		20MAY1999	Mod	N/A	Prob
						HEMATOCRIT 20					
						DECREASED		23JUL1999	Mod	N/A	Prob
						HEMOGLOBIN (7.7)					
						DECREASED		23JUL1999	Mod	N/A	Prob
						HEMATOCRIT (23)					
						HEMATOCRIT 71K		19MAY1999	Mild	N/A	Prob
2/ERICKSON, RICHARD	51 CHS	11FEB1999 16FEB1999	21APR1999 14SEP1999	11AUG1999 14SEP1999	05MAY1999 12MAY1999	LOW PLATELETS 60K		19MAY1999	Mild	N/A	Prob
						ANC, LOW 880		19MAY1999	Mild	N/A	Prob
						02JUN1999		03JUN1999	Mild	N/A	Prob
						LOW HEMOGLOBIN		24JUN1999	Mild	N/A	Prob
						LOW PLATELET 82		21JUL1999	Mild	N/A	Prob
						07JUL1999		28JUL1999	Mild	N/A	Prob
						ANC, LOW 700					
						EMESIS		16MAR1999	Mild	N/A	Prob
						19FEB1999 DEPRESSION					
						23FEB1999 CONSTIPATION					
55 LDR	10SEP1999 14SEP1999	10SEP1999 14SEP1999	21OCT1999 21SEP1999	21OCT1999 21SEP1999	06APR1999 21SEP1999	ACID REFLUX					
						SHORTNESS OF BREATH					
						DRY MOUTH					
						SHORTNESS OF BREATH					
						JOINT STIFFNESS		20SEP1999	Mild	N/A	Prob
						HEADACHE		20SEP1999	Mild	N/A	Prob
						HOT FLASHES		20SEP1999	Mild	N/A	Prob

Date of last treatment (Cytotoxic patients) = - ==> Patient not treated with second Cytotoxic as of data cut-off.  
Date of Resolution = - ==> if date is not given, event is ongoing or date of resolution is unavailable.  
Special Missing values: N = Not Applicable; D = Not Done; A = Not Available; U = Unknown  
All Adverse Events associated with an SAE number have been reported as a Serious Adverse Event only if YES is noted in the Serious column.  
More than one adverse event may have been reported with an SAE. These events are the signs and symptoms of the diagnosis.

AE/SAE Listings  
Adverse Events Possibly/Probably Related to Injection Procedure and/or Study Drug

Randomized Treatment: Gemcitabine

Investigator	Pat Init	Date of Rand	Date of 1st Treatment	Date of Last Treatment	Date of Onset	Adverse Event	SAE Number	Date of Resolut.	Severity	Relationship to:	
										Injection Procedure	Study Drug
2/ERICKSON, RICHARD	55 LDR	10SEP1999	14SEP1999	21OCT1999	29SEP1999	CHILLS		29SEP1999	Mod	N/A	Poss
						(L) SIDE CHEST PAIN					
						NAUSEA					Poss
						WEAKNESS					Poss
						EPIGASTRIC PAIN					Poss
3/KOZAREK, RICHARD	103 EFK	23APR1999	30APR1999	17SEP1999	03MAY1999	RASH ON CHEST		06MAY1999	Mild	N/A	Prob
						NEUTROPENIA					
						THROMBOCYTOPENIA					Prob
						27MAY1999 NEUTROPENIA					Prob
						03JUN1999 NEUTROPENIA					Prob
						12JUN1999 MOUTH SORES					Prob
						26JUL1999 VOMITING					Prob
						NAUSEA					Prob
						02SEP1999 INCREASED FATIGUE FOLLOWING					Prob
						CHEMOTHERAPY					
						03SEP1999 NUMBNESS IN FEET					Prob
						NAUSEA					Prob
						18SEP1999 LEG WEAKNESS					Prob
						22SEP1999 VOMITING					Prob
						DEPRESSION					Prob
106 R-H	09JUL1999	14JUL1999	20OCT1999		16JUL1999	FEVER		01AUG1999	Mild	N/A	Poss
						04AUG1999 NAUSEA					
						11AUG1999 FATIGUE					Poss
						24AUG1999 ANEMIA					Poss
						08SEP1999 I.V. INFILTRATION					Prob
											Prob
											Prob

Date of Last Treatment (Cytomplamt patients) = - ==> Patient not treated with second Cytomplamt as of data cut-off.  
Date of Resolution = - ==> if date is not given, event is ongoing or date of resolution is unavailable.  
Special Missing values: N = Not Applicable; D = Not Done; A = Not Available; U = Unknown  
All Adverse Events associated with an SAE number have been reported as a Serious Adverse Event only if YES is noted in the Serious column.  
More than one adverse event may have been reported with an SAE. These events are the signs and symptoms of the diagnosis.

AE/SAE Listings  
Adverse Events Possibly/Probably Related to Injection Procedure and/or Study Drug

Randomized Treatment: Gemcitabine

Investigator	Pat Init	Date of Rand	Date of 1st Treatment	Date of Last Treatment	Date of Onset	Adverse Event	SAE Number	Date of Resolut.	Severity	Relationship to:	
										Injection Procedure	Study Drug
3/KOZAREK, RICHARD	106 R-M	09JUL1999	14JUL1999	20OCT1999	20OCT1999	NEUTROPENIA		03NOV1999	Mld	N/A	Prob
5/NGUYEN, CUONG	201 JLB	09JUN1999	21JUN1999	13JUL1999	06JUL1999	THROMBOCYTOPENIA		13JUL1999	Mld	N/A	Prob
					13JUL1999	ANEMIA		UUUUUUUU	Mld	N/A	Poss
					15JUL1999	GALLBLADDER FLUID INFECTION +CULTURE		UUUG1999	Mod	N/A	Poss
						GRAM NEG RODS					
	205 EMS	04AUG1999	13AUG1999	18OCT1999	03SEP1999	ANEMIA			Mod	N/A	Prob

Date of Last Treatment (Cytomplamt patients) = - ==> Patient not treated with second Cytomplamt as of data cut-off.  
Date of Resolution = - ==> if date is not given, event is ongoing or date of resolution is unavailable.  
Special Missing values: N = Not Applicable; D = Not Done; A = Not Available; U = Unknown  
All Adverse Events associated with an SAE number have been reported as a Serious Adverse Event only if YES is noted in the Serious column.  
More than one adverse event may have been reported with an SAE. These events are the signs and symptoms of the diagnosis.

END